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K043032

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510 (k) Summary

Oct. 18, 2004

Greg Kennebeck – Contact
Europro, Inc.
3952 Camino Ranchero Rd.
Camarillo, CA 93012
Phone: 800-272-1716
Fax: 805-482-9099

Proprietary Name:	Dealight IPL
Common Name:	Laser Powered Surgical Instrument
Regulation #:	878.4810
Regulatory Status:	Class II
Product Code:	GEX

PRODUCT DESCRIPTION

The Dealight Intense Pulsed Light (IPL) is comprised of the following main components:

- A light / laser system console (including software and control electronics)
- A control and display panel
- Air cooling system
- A hand-piece with cut off filters

INTENDED USE

The Dealight Intense Pulsed Light (IPL) is indicated for use in surgical applications requiring selective photohermolysis (photocoagulation or coagulation) and hemostasis of soft tisse in the medical specialties of general and plastic surgery, and dermatology.

Intense Pulsed Light Energy/Wavelengths (590-1200 nm) are indicated for:

- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

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[1]Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.

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Rationale for Substantial Equivalence

The Dealight is substantial equivalent to Lumenis's/ESC Family of IPL systems (K030342). The Dealight is comparable to the predicate device in terms of the technical specifications, operating performance features, general physical configuration and intended uses.

Safety and Effectiveness Information

The Dealight conforms with federal regulations and performance standards 21 CFR 1040.10 and 21 CFR 1040.11 for medical laser systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Mr. Greg Kennebeck
Europro, Inc.
3952 Camino Ranchero Road
Camarillo, California 93012

Re: K043032
Trade/Device Name: Dealight IPL
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 10, 2005
Received: June 14, 2005

Dear Mr. Kennebeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510 (k) Number: K043032
Device Name: Dealight IPL

Intense Pulsed Light Energy/Wavelengths (590-1200 nm) are indicated for:

- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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